Remarks

The Office Action mailed October 23, 2001 has been received and reviewed. Claims 1 through 23 are currently pending. Claims 7, 8, 11 and 16 through 18 have been canceled without prejudice or disclaimer. Claims 1 through 6, 9, 10 and 12 through 23 stand rejected. Applicants have amended claims 1 through 6, 9, 10, 12 through 15, 19 through 21 and 23. Applicants respectfully request reconsideration in view of the amendments and remarks herein.

1. Specification

Applicants note with appreciation that the published abstract has been placed in the instant application as page 30. Applicants have amended the specification to include section headings as suggested by the Examiner.

2. 35 U.S.C. §112, second paragraph

Claims 1 through 6, 9, 10 and 12 stand rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Specifically, claim 1 was rejected for inclusion of the term "certain". Applicants have removed this term from claim 1 and request withdrawal of the rejection.

Claim 2 was rejected for inclusion of the term "the vaccine or preparation". Applicants have amended claim 2 to recite "the vaccine". Claim 2 was also rejected for reciting "has been administered" because it was not clear to whom or to what subject the vaccine is administered. Applicants have amended claim 2 to recite "administration of the vaccine to a subject" and request withdrawal of the rejections.

Claim 6 was rejected for inclusion of the language "peptide consisting essentially of". Applicants have removed the term "essentially" and request withdrawal of the rejection.

3. 35 U.S.C. 102

Claims 1-4, 12, 13, 19, 22 and 23 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent 5,256,641 to Yatvin et al. (hereinafter "Yatvin").

Applicants respectfully submit that Yatvin fails to teach every element of the claims. Yatvin discloses a method of facilitating the entry of antigenically-active peptides into cells and for delivering such peptides to the appropriate intracellular organelles for immunological processing and antigen presentation. (Yatvin, col. 5, lines 55-60). Yatvin further discloses conjugating the desired antigenically-active peptide to a polar lipid carrier through a spacer moiety. (Id. at col. 5, lines 65-68; col. 6, lines 1-8, col. 8, lines 6-12 and FIG. 5). By way of contrast, independent claims 1, 13 and 19 recite a direct link between a peptide or antigen and a fatty acid or fatty acid-peptide carrier.

As Yatvin fails to teach every element of the present invention, applicants submit that claims 1 through 4, 12 13, 19, 22 and 23 are not anticipated by Yatvin. Reconsideration and withdrawal of the rejection is requested.

4. 35 U.S.C. 103

Claims 1, 5, 13, 14, 19 and 20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,256,641 to Yatvin et al. or U.S. Patent 5,013,548 to Haynes et al. in view of Wiedemann et al. Claims 1 through 6, 9, 10 and 12 through 23 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 6,284,733 to Meleon et al. in view of Wiedemann et al.

Applicants submit that neither Yatvin nor Haynes teaches or suggests a direct link between a peptide (or antigen) and a lipid or other carrier compound as recited in the claims. The discussion of Yatvin above is incorporated herein. Haynes discloses immunogenic preparations of peptides comprising amino acid sequences corresponding to antigenic determinants of the envelope glycoprotein of HIV coupled to a carrier molecule. Haynes discloses conjugating the peptide to the carrier molecule through a heterofunctional coupling agent. (Haynes, col. 5, lines 15-23). The preferred coupling agents are M-maleimidobenzoyl-N-hydroxysuccinimide ester (MBS) or the water soluble compound m-maleimidobenzoylsulosuccinimide ester. (Id.) In an alternate embodiment, Haynes discloses coupling the peptide and carrier molecule through a spacer. (Haynes, col. 5, lines 1-5). Such is not the present invention as the claims recite a direct link between a peptide (or antigen) and a lipid or other carrier compound.

The Office acknowledged that neither Yatvin nor Haynes discloses the use of a palmitic acid carrier. (Paper No. 17, page 7). Wiedemann was cited as disclosing this element. However, the P_3CS constructs disclosed in Wiedermann are complex molecules consisting of three palmitic acids, bound via ester or amide bonds to cysteine. These complex molecules are quite different from the simple palmitic acid taught in the present application as the P_3CS constructs lack labile binding under physiological conditions. By way of contrast, in the present application, the antigen or peptide and carrier compound are coupled in a "reversible and labile way". (Specification, Abstract). Therefore, the conventional use of P_3CS as a carrier in peptide conjugates would not make it obvious, to one of ordinary skill in the art at the time of the invention, to substitute Yatvin's generic fatty acid or Haynes' protein carrier molecule with Widemann's specific P_3CS adjuvantic carrier to produce the vaccine or composition of the instant application. Reconsideration and withdrawal is requested.

Meleon also lacks disclosure of labile binding under physiological conditions. Accordingly, the proposed combination of Meleon and Widemann cannot render the present invention obvious. Reconsideration and withdrawal of the rejection is requested.

5. Claim Objections

Claims 12 and 23 were objected to for inclusion of the term "with pharmaceutically acceptable carrier" without a preceding article. Applicants have amended the claims to recite "with a pharmaceutically acceptable carrier" as suggested by the Examiner and request withdrawal of the objection.

Further, applicants have amended claims 1 and 19 to recite "fatty acid-peptide carrier" as suggested by the Examiner and request withdrawal of the objection. Claims 6, 15, and 21 have been amended to recite "SEQ ID" as suggested by the Examiner. Additionally, applicants have amended claims 15 and 21 to remove non-elected peptide sequences.

Conclusion

In view of the amendments and remarks, applicants respectfully submit that the amended claims define patentable subject matter. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,

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Enclosures:

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APPENDIX A
VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A vaccine comprising an antigen and a fatty acid or fatty acid-peptide carrier compound which are directly [or indirectly] linked by a thioester or a [disulphide] disulfide bond that is labile and dissociates under [certain] physiological conditions.

2. (Amended) [A] The vaccine according to claim 1, [in which] wherein said antigen dissociates from said fatty acid-peptide carrier compound after administration of the vaccine to a subject [or preparation has been administered].

3. (Twice amended) [A] The vaccine according to claim 1, [in which] wherein said antigen is a protein, a polypeptide, a synthetic peptide, a carbohydrate, or a hapten.

4. (Amended) [A] The vaccine according to claim 3, [in which] wherein the antigen is a synthetic peptide.

5. (Twice amended) [A] The vaccine according to claim 1, [in which] wherein the fatty acid is palmitic acid.

6. (Amended three times) [A] The vaccine according to claim 4, wherein the synthetic peptide [essentially] consists of the amino acid sequence of [SEQ. I.D. NO.] SEQ ID NO: 1.

9. (Twice amended) [A] The vaccine according to claim 1, [in which] wherein the antigen is a peptide and the carrier compound is another copy of said peptide coupled to a fatty acid.

10. (Amended) [A] The vaccine according to claim 9, [in which] wherein the carrier compound is an N-palmitoylated peptide.

12. (Twice amended) [A] The vaccine [preparation] according to claim 1 together with a pharmaceutically acceptable compound or adjuvant.

13. (Amended) A composition comprising a synthetic peptide directly linked with a thioester bond to a fatty acid.

14. (Amended) [A] The composition according to claim 13, wherein the fatty acid is palmitic acid.

15. (Amended three times) [A] The composition according to claim 13, wherein the peptide is [selected from the group consisting of SEQ. I.D. NO.] SEQ ID NO: 1[, SEQ. I.D. NO. 2 and SEQ ID NO. 3].

19. (Amended) A method for producing an immunogenic preparation comprising directly linking a synthetic peptide with a fatty acid or fatty acid-peptide carrier compound via a thioester or [disalphide] disulfide bond that is labile and dissociates under [certain] physiological conditions.

20. (Amended) [A] The method according to claim 19, wherein the fatty acid is palmitic acid.

21. (Twice Amended) [A] The method according to claim 19, wherein the peptide is [selected from the group consisting of SEQ. I.D. NO.] SEQ ID NO: 1[, SEQ. I.D.] SEQ ID NO. 2 and SEQ ID NO. 3].

23. (Amended) A vaccine comprising an immunogenic preparation according to claim 22 together with a pharmaceutically acceptable compound or adjuvant.